UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	Master File No. 06 MD 1789 (JFK)
This document relates to: Scheinberg v. Merck & Co., Inc., No. 08 Civ. 4119 (JFK)	**OPINION & ORDER**

APPEARANCES

For Plaintiff Rhoda Scheinberg:

LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.
By: Timothy M. O'Brien, Esq.
Brandon L. Bogle, Esq.

For Defendant Merck Sharp & Dohme Corporation:

HUGHES HUBBARD & REED LLP
By: Theodore V. H. Mayer, Esq.
William J. Beausoleil, Esq.
Julia R. Zousmer, Esq.

VENABLE LLP
By: Paul F. Strain, Esq.
David J. Heubeck, Esq.
Stephen E. Marshall, Esq.

JOHN F. KEENAN, United States District Judge:

I. The Motions

This is the fifth case selected for trial as a bellwether in the In re Fosamax Products Liability Litigation multidistrict litigation. This MDL involves claims that Fosamax, a drug designed and produced by defendant Merck Sharp & Dohme Corp. ("Merck"), caused users of Fosamax to suffer from a condition known as osteonecrosis of the jaw ("ONJ"). In the instant case, plaintiff Rhoda Scheinberg ("Scheinberg" or "Plaintiff") brings

strict liability and negligence claims on theories of design defect and failure to warn, in addition to claims for fraudulent misrepresentation and concealment, and breach of express and implied warranty. Plaintiff also seeks punitive damages.

Before the Court are four motions: (1) Merck's motion for summary judgment against Plaintiff on all claims; (2) Merck's motion to preclude Plaintiff's proposed expert testimony of Dr. Suzanne Parisian; (3) Merck's motion to preclude Plaintiff's proposed expert testimony of Drs. Sanford Buch and Andrew Breiman; and (4) Plaintiff's motion to preclude Merck's proposed expert testimony from Drs. Barry Gruber and Robert Glickman. For the reasons set forth below, Merck's motion for summary judgment is granted with respect to Plaintiff's claims for breach of warranty, fraudulent misrepresentation and concealment, and punitive damages, but denied with respect to Plaintiff's claim for design defect and failure to warn. Merck's motions to preclude expert testimony are granted in part and denied in part. Plaintiff's motion to preclude expert testimony is granted in part and denied in part.

II. Background

Defendant Merck is a New Jersey-based pharmaceutical company that makes and distributes the drug alendronate sodium under the brand name Fosamax. Fosamax is one of several drugs known as "bisphosphonates," and is taken orally, rather than

intravenously as are some other bisphosphonates. Fosamax was originally approved by the FDA for the treatment of postmenopausal osteoporosis and Paget's disease in 1995, and the FDA has since approved it for additional uses.

Plaintiff contends that Merck has long known of reports linking bisphosphonate use with the development of ONJ. According to Plaintiff, Merck was aware that Fosamax could cause ONJ before Scheinberg suffered her injuries, and Merck failed adequately to warn the medical community of this risk. Plaintiff references various adverse event reports suggesting complications allegedly related to ONJ in persons being treated with Fosamax, as well as twenty later, more definitive reports in the 2003-2005 timeframe that Fosamax users were experiencing symptoms of ONJ.

Merck claims that after receiving reports that Fosamax users were developing ONJ, its various research teams began to investigate the reports by calling physicians and attempting to ascertain "background rates" for the incidence of ONJ in the population of those who do not use Fosamax. These research teams first recommended that Merck change its label to include an ONJ warning in January 2005. Eventually, after seeking FDA approval, Merck modified its label in July 2005, to inform the public that: "Osteonecrosis of the jaw, generally associated

with tooth extraction and/or local infection, often with delayed healing, has been reported in patients taking bisphosphonates."

Scheinberg began taking Fosamax in 2000, and continued taking it through 2006. Her prescribing physician between 2004 and 2006 was Dr. Dunn. (Def. 56.1 ¶ 1.) On October 30, 2006, Plaintiff had a tooth extraction, after consultation with her dentist, Dr. Rinaudo and an oral surgeon, Dr. Buch. (Id. ¶¶ 3-4.) Plaintiff's proffered expert, Dr. Richard Kraut, has opined that the delay Plaintiff experienced in healing from the tooth extraction was ONJ, and that her use of Fosamax "was a major contributing factor to her development of ONJ." (Kraut Report at 8.) Dr. Kraut also stated that to avoid the onset of ONJ, Scheinberg would have needed to stop taking Fosamax at least six months before her tooth extraction, or April 30, 2006. (Kraut Depo. at 141:2-25, 148:25-149:7.)

III. Defendant's Motion for Summary Judgment

The parties do not dispute that Plaintiff's claims are governed by New York law. The Court notes that Scheinberg is a resident of New York. (Compl. ¶ 1.)

A. Design Defect

Merck argues that summary judgment is warranted on Scheinberg's design defect claim because she has not presented any expert testimony that there was a feasible design alternative.

In response, Plaintiff suggests that under New York law, a feasible design alternative is only one of many factors for a jury to consider in a design defect claim. Voss v. Black & Decker Mfg. Co., 450 N.E.2d 204, 208-09 (N.Y. 1983). In any event, Plaintiff states, she has adduced evidence of two alternative designs that Merck could have employed. First, Plaintiff avers that for patients like Scheinberg, whose T-scores were better than -2.5, the placebo is just as effective, and therefore it could constitute a feasible alternative design. Second, Plaintiff asserts that Dr. Parisian has testified that Merck should have included a warning about ONJ on its packaging. As such, Plaintiff proffers that a feasible design alternative could be the same product (Fosamax), repackaged to include a much stronger warning.

Under New York law, a plaintiff may recover for a design defect by showing that the product, as designed, was not reasonably safe and that the defective design was a substantial factor causing the plaintiff's injury. See id. at 108–09. To recover under a theory of strict products liability for sale of a defectively designed product, "it is well established that a plaintiff must plead and prove that there was a feasible design alternative that would have made the product safer." Daley v. McNeil Consumer Products Co., a Div. of McNeil-PPC, Inc., 164 F.Supp.2d 367, 374 (S.D.N.Y. 2001).

Despite Plaintiff's assertion that he is not required to prove evidence of alternative machine designs, the Second Circuit case which she cites for that proposition specifically provides that "it is true that the plaintiff carries the burden of showing that an alternative design was feasible and safer," in connection with a claim for design defect. Urena v. Biro Manu. Co., 114 F.3d 359, 365 (2d Cir. 1997). Indeed, Urena held only that the plaintiff in that case was able to meet the burden without considering the testimony of his proposed expert. Id.

Plaintiff has misinterpreted the law as to whether evidence of a feasible alternative design is a prerequisite for a design defect claim. However, she is correct in asserting that a different label on the outside of the Fosamax container would be a sufficient "feasible alternative design," the adequacy of which is for the jury to decide. Indeed, the Second Circuit has held that testimony as to whether a manufacturer could "have added a sticker or other warning to the machine which would have made clear" the risk associated with using the product is sufficient evidence of a feasible alternative design. Urena, 114 F.3d at 365. Therefore, summary judgment as to the design defect claim is denied.

B. Failure to Warn

Merck next argues that it is entitled to summary judgment on Scheinberg's failure to warn claim because (1) no warning

would have changed Scheinberg's doctors' prescribing decisions and (2) Merck's warnings were sufficient as a matter of law. In support of this argument, Merck points to Dr. Dunn's statements that Merck's 2005 label change "apprised" her of the "possible risk of necrosis of the jaw for patients [who] take Fosamax." (Dunn Depo. 138, 246.) Dr. Dunn also stated that even the 2012 Fosamax label "would not have changed [her] decision to continue [Plaintiff] on Fosamax from 2004 to 2006." (Id.)

Plaintiff responds that Merck has misread Dunn's testimony, pointing to another two statements Dr. Dunn made: first, that if she had "been aware in 2005 or 2006 that Fosamax can induce death of the jaw bone," she may have changed her prescribing practices; second, that a "Dear Doctor" letter would have made her aware that patients like Scheinberg were at risk for ONJ. Specifically, Dr. Dunn testified that if she had received a "Dear Doctor" letter, she would have prescribed Fosamax less frequently, particularly to patients with suboptimal oral health or who may need a tooth extraction. (Dunn Depo. 193-94.)

Moreover, Plaintiff maintains that the 2005 label was inadequate as a matter of law, as there is sufficient evidence that Merck failed to warn both the medical community as a whole and Scheinberg's prescribing physician about the risk of ONJ. Plaintiff further states that Merck did not take the additional steps necessary – such as distributing a "Dear Doctor" letter –

to convey the risks associated with Fosamax to the medical community. To support these allegations, Plaintiff points to testimony from Dr. Parisian and Dr. Dunn, both of whom underscored the importance of a "Dear Doctor" letter.

Under New York law, a failure to warn claimant must show (1) that a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known and (3) that failure to do so was the proximate cause of harm. Failure to warn claims are analyzed the same way under strict liability and negligence theories of recovery. See Anderson v. Hedstrom Corp., 76 F. Supp. 2d 422, 439 (S.D.N.Y. 1999) ("Where liability is predicated on failure to warn, New York views negligence and strict liability claims as equivalent."); see also Denny, 87 N.Y.2d at 258 ("Failure to warn claim . . . couched in terms of strict liability, is indistinguishable from a negligence claim.").

New York's "heeding presumption" dictates that the Court must presume that a user would have heeded warnings if they had been provided, and that the injury would not have occurred. See Anderson, 76 F. Supp. 2d at 441. This presumption may only be rebutted by specific facts showing that the warning would have been futile. See id.

Given Dr. Parisian's testimony that the 2005 label change was inadequate, the only issue on summary judgment is whether

Plaintiff has established proximate cause. To establish proximate causation in a failure to warn claim resulting from a pharmaceutical product, a plaintiff must show that an appropriate warning would have affected the course of treatment of the plaintiff's physician. In re Fosamax Prods. Liab. Litig., No. 06-MD-1789, 2010 WL 1257299, at *5 (S.D.N.Y. March 26, 2010).

Although Merck would have the Court consider only Dr. Dunn's testimony that supports its position, the fact remains that she has provided conflicting testimony on whether additional information about Fosamax would have impacted her decision making. Dr. Dunn told attorneys that if she had "been aware in 2005 or 2006 that Fosamax can induce death of the jaw bone," she would have changed her prescribing practices, yet also testified that the label "apprised" her of the risk of ONJ. There is obviously a question of fact as to whether different warnings could have changed Dr. Dunn's prescribing practice. It is for the jury to decide which of her statements to credit. See Liriano, 92 N.Y.2d at 243 (noting that failure to warn is typically a fact-intensive inquiry for the jury to decide).

C. Breach of Warranty (Express and Implied)

In moving for summary judgment on the breach of express warranty claim, Merck argues that it never made any affirmative statements of fact in connection with Fosamax. Moreover, Merck

notes, the Plaintiff herself admitted that she did not see any advertisements for Fosamax.

Plaintiff responds that simply because Plaintiff did not see any advertisements for Merck does not mean that Merck did not make any express warranties. In a declaration dated December 7, 2012, Scheinberg asserts that she "recalls reading" the Fosamax patient handout from 2000. Scheinberg further states that she relied upon the misrepresentation that Fosamax would prevent fractures, and that if she knew this were false, she would not have continued taking Fosamax. (Scheinberg Decl. Dec. 7, 2012.) This testimony, according to Plaintiff, establishes that she received an express warranty from Merck.

To state a claim for breach of express warranty, the plaintiff must show that there was an "affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase, and that the warranty was relied upon." Schimmenti v. Ply Gem Indus., Inc., 156 A.D.2d 658 (2d Dep't 1989) (quoting Friedman v. Medtronic, Inc., 42 A.D.2d 185 (2d Dep't 1973)).

Plaintiff testified at deposition that she never read the 2005 patient handout, and did not see any advertisements. The colloquy went as follows:

> Q. I assume you don't recall when you first heard about Fosamax. Right?
> A. As a drug to take?

Q. At all, the first time you ever heard the word Fosamax.
A. I don't remember, but I remember having a conversation with someone and it was supposed to be the wonder drug on the market.
Q. The wonder drug on the market for what?
A. For helping your bones.
Q. And you don't remember if that conversation was with Dr. Hupart or with Dr. Kaplan?
A. No. I can't help you.
Q. Do you remember ever doing any research on your own into Fosamax?
A. When I was taking it? No.
Q. You indicated in your profile form that you never saw any advertisements, commercials, or other types of advertisements for Fosamax before you started taking it.
A. No, I've never – I never saw it while I was taking it either.

(Scheinberg Depo. 218-19.)

Plaintiff's recently executed declaration states that she read the patient insert when she began taking the medication. "In reading the patient insert, it informed me and I understood from reading it that Fosamax would prevent fractures in patients like me." (Scheinberg Decl. Dec. 7, 2012) She goes on to say that she relied on this information in taking Fosamax, and that she would not have taken it if she had known that it did not prevent fractures.

Under the law in this Circuit, a Court considering a motion for summary judgment may not rely on an affidavit that contradicts a party's deposition testimony. Mack v. United States, 814 F.2d 120, 124 (2d Cir. 1987) ("It is well settled in this circuit that a party's affidavit which contradicts his own prior deposition testimony should be disregarded on a motion for

summary judgment"); Raskin v. The Wyatt Company, 125 F.3d 55, 63 (2d Cir. 1997) ("[W]e follow the rule that a party may not create an issue of fact by submitting an affidavit in opposition to a summary judgment motion that, by omission or addition, contradicts the affiant's previous deposition testimony."). In the present case, there is a conflict between the plaintiff's sworn testimony and her affidavit. The former indicates that plaintiff did not receive any express warranties from Merck, while the affidavit drafted for this motion avers the contrary. The Court treats plaintiff's deposition testimony as true for purposes of this motion. Accordingly, Plaintiff has failed to demonstrate that Merck made an affirmation of fact upon which she relied. Plaintiff's motion for summary judgment on the express warranty claim is therefore denied.

Merck next argues that it is entitled to summary judgment on the breach of implied warranty claims because the Plaintiff has failed to show that Fosamax was not minimally safe. Merck proffers that 270 reported cases of ONJ among millions of users of Fosamax is not a significant incidence rate. Merck argues that the Plaintiff has presented no authority for the proposition that such a low number of reports of ONJ should lead a court to conclude that the product is not minimally safe.

Plaintiff responds that there are issues of fact related to whether Fosamax is minimally safe, proffering that the incidence

rate of ONJ among Fosamax users is not as infinitesimal as Merck suggests. Indeed, Plaintiff avers, peer-reviewed prevalence studies reveal a higher incidence rate: a study by the University of Southern California put the incidence rate at 4% while the National Institutes of Health found that 1 in 952 Fosamax users contracted ONJ. Moreover, Plaintiff cites various New York cases for the proposition that courts should not require a certain number of adverse events per capita before determining whether a product is minimally safe.

A manufacturer may be held liable under New York law for breach of implied warranty when its products are not "fit for the ordinary purposes for which such goods are used." N.Y. U.C.C. § 2–314(2)(c). Specifically, a Plaintiff may recover "upon a showing that [a] product was not minimally safe for its expected purpose," and the focus of a breach of implied warranty inquiry is whether the product meets "the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners." Denny, 87 N.Y.2d at 258–59.

Accordingly, summary judgment on the implied warranty claim hinges on whether Fosamax was "minimally safe." As an initial matter, the Court notes that it has previously found that "the risk for ONJ is small." The Court has further found that

> The FDA approved Fosamax in 1995 for the treatment of osteoporosis and Paget's disease and in 1997 for the prevention of osteoporosis. Fosamax was the first of three

> nitrogen-containing bisphosphonates approved for oral administration to treat these conditions. Since their market introduction, oral bisphosphonates have been prescribed by doctors over 225 million times. The efficacy of these drugs in arresting bone loss and reducing the risk of fracture in osteoporotic persons is well-established.

In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 171 (S.D.N.Y. 2009). In opposing the instant motion for summary judgment, Plaintiff has failed to adduce sufficient evidence for the Court to find that Fosamax is not minimally safe, given that millions of prescriptions for Fosamax have been issued, and that Fosamax has been proven effective for fracture reduction. The incidence rate of ONJ among Fosamax users is so low that no reasonable juror could conclude that Fosamax was not minimally safe. See Daley v. McNeil Consumer Prods. Co., 164 F. Supp. 2d 367, 374 (S.D.N.Y. 2001) (granting summary judgment on Plaintiff's breach of implied warranty claim on the grounds that no more than a small "fraction of potential users" reported an adverse reaction). Therefore, Merck is entitled to summary judgment on the breach of implied warranty claim.

D. Fraudulent Concealment and Fraudulent Misrepresentation

Merck next moves for summary judgment on Plaintiff's fraudulent misrepresentation and concealment claims. The Complaint alleges that Merck made two misrepresentations that concealed two valuable pieces of information. First, Plaintiff avers that Merck falsely represented that Fosamax was safe for

osteoporosis and Paget's disease, which concealed Fosamax's substantial risks. Second, Plaintiff states that Merck falsely represented that Fosamax was safer than the alternatives on the market, concealing the fact that it was not safer than alternatives. According to Merck, there is no evidence that either of those statements is false.

To state a claim for fraudulent misrepresentation under New York law, a plaintiff must show: "(1) the defendant made a material false representation, (2) the defendant intended to defraud the plaintiffs thereby, (3) the plaintiffs reasonably relied upon the representation, and (4) the plaintiffs suffered damage as a result of their reliance." Swersky v. Dreyer & Traub, 219 A.D.2d 321 (N.Y. 1996). A claim for fraudulent concealment requires the same showing as that for fraudulent misrepresentation, with the additional requirement that the plaintiff must demonstrate that the defendant had a duty to disclose material information. See Banque Arabe, 57 F.3d at 153; Allied Irish Banks, P.L.C. v. Bank of America, N.A., No. 03 Civ. 3748, 2006 WL 278138, at *6 (S.D.N.Y. Feb. 2, 2006). For both forms of fraud, the element of damage includes a requirement that the plaintiff establish proximate causation. See, e.g., Hunt v. Enzo Biochem, Inc., 471 F. Supp. 2d 390, 399-400 (S.D.N.Y. 2006) (stating that a claim of common law fraud under New York law "requires a showing of proximate causation").

Plaintiff has failed to show that Merck's statement that Fosamax is "safe and effective for the treatment of osteoporosis and Paget's disease" is false. Specifically, there is no evidence that Fosamax is ineffective in treating those diseases. As the Court has found, "[b]y all estimates, the risk of developing ONJ while taking an oral bisphosphonate for osteoporosis is very small." In re Fosamax Prods. Liability Litig., 645 F. Supp. 2d at 171.

Moreover, Dr. Dunn has testified that she was "apprised" of the possible risk of ONJ, invalidating Plaintiff's assertion that Merck concealed information of the risk of ONJ from prescribing physicians. Therefore, Merck is entitled to summary judgment on the fraudulent concealment and misrepresentation claims.

E. Punitive Damages

Merck argues that punitive damages are reserved only for the "singularly rare cases" in which the Defendant is proven to have acted intentionally or with wanton disregard. Merck reminds the Court that it has twice ruled that Merck's conduct before the 2005 label change was not wanton or intentional. Merck urges that the fact that it issued a label change in 2005 provides even more support for the assertion that it did not "consciously disregard" the safety of others.

Plaintiff insists that Merck acted willfully because New York law provides that fraud may be predicated on a defendant's "concealment, if the defendant had a duty to disclose." Plaintiff states that Merck continually and systematically "grossly overstated the efficacy of Fosamax" in an attempt to "shift the treatment threshold" and persuade doctors to prescribe Fosamax to more patients. Plaintiff also points to evidence that the FDA issued warnings to Fosamax about its "misleading" advertisements. Finally, Plaintiff states that Merck delayed changing the label and "cooked the books" in an attempt to downplay the incidence of ONJ.

There is no additional evidence in this case to cause the Court to permit this Plaintiff to assert a claim for punitive damages. In denying punitive damages on theories of intentional and grossly negligent conduct in Boles, the Court found "no evidence – let alone clear and convincing evidence – that Merck had 'actual knowledge' of the 'high probability' that Fosamax would cause Boles to develop ONJ." In re Fosamax Prods. Liab. Litig., 647 F. Supp. 2d 265, 284 (S.D.N.Y. 2009). Boles involved a claimed injury date of September 2003, and at that point in time the only evidence of any possibility that Fosamax caused ONJ included "a handful of reports of exostosis from the mid- to late-1990s." Id. Here, Plaintiff has not presented any additional evidence that would lead the Court to believe

punitive damages are appropriate. Indeed, Merck had taken more steps with respect to informing the medical community of adverse events by the time of Scheinberg's injury.

Given the small number of ONJ cases relative to the total number of Fosamax users, there is no evidence in this case suggesting that Merck concealed information about the efficacy of Fosamax. There is no evidence to suggest that Merck had an awareness of a "high probability" that Fosamax caused ONJ, and Plaintiffs' assertions that Merck simply ignored the reports of ONJ are without merit. On the evidence presented by Plaintiff, no reasonable jury could conclude that Plaintiff would be entitled to punitive damages. Therefore, Merck's motion for summary judgment is granted with respect to Plaintiff's claims for punitive damages.

IV. Defendant's Daubert Motions

A. Legal Standard

The presentation of scientific and technical knowledge or opinion testimony by a "witness qualified as an expert" is permitted under Rule 702 of the Federal Rules of Evidence where such testimony:

> (1) will assist the trier of fact to understand the evidence or to determine a fact in issue
> (2) is based upon sufficient facts or data,
> (3) is the product of reliable principles and methods; and
> (4) results from the reliable application of principles and methods . . . to the facts of the case.

Fed. R. Evid. 702. In making a determination about whether to admit proposed expert testimony, the Second Circuit has held that "the district court should consider the indicia of reliability identified in Rule 702," specifically items 2-4 listed above. Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 265 (2d Cir. 2002) (internal quotation marks omitted). The "reliable principles and methods" prong of Rule 702 analysis requires the Court to look to other factors in order to fulfill its designated "gatekeeping" role, such as:

> (1) whether a theory or technique has been or can be tested;
> (2) whether the theory or technique has been subjected to peer review and publication;
> (3) the technique's known or potential rate of error and the existence and maintenance of standards controlling the technique's operation; and
> (4) whether a particular technique or theory has gained general acceptance in the relevant scientific community

United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007) (citing Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 593-94 (1993)). The purpose of analyzing proposed expert testimony in light of Rule 702 and Daubert reliability factors is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999).

B. Drs. Sanford Buch and Andrew Breiman

Merck asks the Court to preclude both of Plaintiff's treating surgeons – Drs. Sanford Buch and Andrew Breiman – from giving specific causation opinion testimony because neither has ever diagnosed Plaintiff with ONJ. Merck argues that these doctors' opinions do not satisfy the Daubert test.

At the outset, Plaintiff argues that a treating physician's fact testimony or observation testimony does not implicate Daubert. Plaintiff urges the Court to refrain from conducting a Daubert analysis because this testimony "sets a framework and reference point for subject expert testimony from the parties' respective expert witnesses." Plaintiff misperceives the Daubert inquiry. Although Daubert need not apply to a treating physician's fact or observation testimony, the testimony at issue here is Dr. Buch's opinion that Fosamax caused Scheinberg's ONJ. As this Court previously held, a treating doctor's "opinion on causation is subject to the same standards of scientific reliability that govern the expert opinion of physicians hired solely for the purposes of litigation." In re Fosamax Prods. Liab. Litig., 2009 WL 4042769 (S.D.N.Y. Nov 23, 2009). Therefore, the testimony in question will be subject to Daubert.

The Court will now analyze the admissibility of each doctor's testimony in turn.

i. Motion To Preclude Dr. Buch from Giving A Specific Causation Opinion

Dr. Buch, who performed Scheinberg's tooth extraction on October 30, 2006, testified that (1) Scheinberg's jaw bone was necrotic and (2) her post-tooth extraction delayed healing was "consistent with Fosamax's effect on delayed healing following tooth extraction." Merck seeks to preclude this testimony because Dr. Buch also stated that he never diagnosed Scheinberg with ONJ and that he could not offer an opinion on whether Fosamax was related to the ONJ. His deposition testimony is as follows:

> Q: When you say that you thought there might be a problem, I don't see in your note any diagnosis of any specific problem –
> A: I didn't make any diagnosis. I just – from an extraction site that long afterwards where the patient was developing swelling, that something just wasn't right with it.
> ***
> Q: So earlier and throughout the deposition, when you mentioned that [Plaintiff] had osteonecrosis of the jaw, it's not a condition that you diagnosed her with, right?
> A: No, I did not diagnose that.
> Q: And when you say that she had osteonecrosis of the jaw, what is your basis for that?
> A: I don't have a basis. Someone else made the diagnosis. I very much assume that's a correct diagnosis.
> Q: Do you know that somebody else actually diagnosed her with that?
> A: And I told you I don't know how I knew, but it was mentioned.
> Q: By whom?
> A: I don't know.
> * * *
> Q: Since you haven't seen [Plaintiff] since December 7, 2006, I take it you don't intend to offer any opinion

testimony in this case about whether or not her Fosamax use was or was not related to her jaw condition?
A: I don't think I can make that statement.
(Buch Depo. 70–72, 73.)

According to Merck, given that Dr. Buch did not make the ONJ diagnosis, his testimony that Scheinberg's jaw condition was "consistent with Fosamax's effect on delayed healing" is insufficient causation evidence because it does not reflect any "sense of certainty." Therefore, Merck avers that Dr. Buch should be precluded from offering an opinion on specific causation.

In response, Plaintiff notes that the issue of whether Scheinberg had ONJ is not disputed in this case. Plaintiff also argues that the "consistent with" language has been permitted by this Court in the past. (Pl. Opp. at 5 ("In the Maley case, because plaintiff's expert Dr. Redfern testified as to general causation, he properly relied on findings of other physicians, including a 'pathology report of findings consistent with dead or dying bone.'").)

Dr. Buch's deposition testimony precludes him from drawing the conclusion that Fosamax caused Scheinberg's ONJ. Having told Merck attorney's that he "can [not] make [the] statement" that Scheinberg's jaw condition was related to her Fosamax use, he has demonstrated that he is not in a position to render an

opinion as to causation. Therefore, Dr. Buch's opinion as to causation is inadmissible.

ii. Motion To Preclude Dr. Breiman from Giving a Specific Causation Opinion

Merck next argues that Dr. Breiman's testimony as to specific causation does not reflect sufficient medical certainty. Dr. Breiman saw Plaintiff on two occasions, December 12 and 13, 2006. During Scheinberg's visits, Dr. Breiman observed swelling in her jaw, determined that there was an infection, and attempted to drain the excess fluid in her jaw. He then referred her to another facility for examination. At deposition, Dr. Breiman confirmed that he never diagnosed Scheinberg with ONJ and could not opine about the effects of Fosamax:

> Q: Did you, Doctor, ever diagnose [Plaintiff] with osteonecrosis of the jaw?
> A: No.
> Q: Or bisphosphonate related osteonecrosis of the jaw?
> A: No.
> * * *
> Q: Am I correct, you did not make a determination as to whether [Plaintiff's] Fosamax use caused her oral cavity condition?
> A: Correct.
> * * *
> Q: Based on your testimony, you are saying that you do not know whether Fosamax was or was not the cause of the jaw problems she presented with in December '06?
> A: Correct.
> Q: That, again, is because you just don't have enough information to inform you as to that?
> A: Correct.

(Breiman Depo. 60-61, 72.)

Dr. Breiman also stated at deposition that he did include bisphosphonate-related ONJ in his differential diagnosis. (Id. at 60.) A "differential diagnosis" is a "patient-specific process of ruling out potential causes of an illness as unlikely until one case remains." Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 251 (2d Cir. 2005). Merck argues that because bisphosphonates were considered as one of many possible causes of Plaintiff's jaw condition, Dr. Breiman's opinion on specific causation is not to any degree of medical certainty.

In response, Plaintiff argues that Merck is advancing a double standard by seeking to exclude evidence that Dr. Breiman considered Fosamax as a potential cause of Scheinberg's ONJ while admitting the fact that he considered other possibilities. (Pl. Mot. at 11 ("If this Court were to grant Defendant's Daubert motion as to the differential testimony, by that same logic it will also exclude testimony regarding the non-bisphosphonate factors which would have made it on to Dr. Breiman's differential list.").)

Dr. Breiman is precluded from offering specific causation testimony for the same reason Dr. Buch's testimony on that subject is precluded: Dr. Breiman testified that he did not "have enough information" to determine whether Fosamax caused her ONJ. "While an expert need not rule out every potential

cause in order to satisfy Daubert, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant." Israel v. Spring Indus., No. 98 Civ. 5106, 2006 WL 3196956, at *5 (E.D.N.Y. Nov. 3, 2006). Here, Dr. Breiman admitted that he could not eliminate other potential causes, rendering his testimony inadmissible. Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 202 (4th Cir. 2001) ("[I]f an expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert's testimony.").

Plaintiff's argument that Merck is attempting to use Daubert as both a sword and a shield is irrelevant, as the Court's ruling only goes to whether Dr. Breiman can testify as to specific causation. The Court will not rule as to other proposed testimony until it is presented with the deposition designations.

C. Dr. Suzanne Parisian

Although Dr. Parisian has been admitted as an expert in prior bellwether trials, she served a supplemental report in October 2012, which contains opinions regarding the adequacy of the 2005 label change. Merck objects to sixteen of Dr. Parisian's newly submitted opinions.

i. Opinion that the 2005 Label Did Not Warn of the Association Between Fosamax and ONJ

Merck urges the Court to exclude Dr. Parisian's opinion that the July 2005 Fosamax label did not inform prescribing physicians that there was an association between Fosamax and ONJ. Merck argues that Dr. Parisian cannot presume to know how a prescribing physician would interpret the label. Moreover, Merck avers that Dr. Parisian's opinion is irrelevant to the facts of this case because it would not have affected Dr. Dunn's prescription decisions, given that Dr. Dunn testified that she knew there was a "possible risk of necrosis of the jaw for patients [who] take Fosamax."

Plaintiff responds that Dr. Parisian's testimony is not premised on the internal thoughts of an individual physician; rather, it is premised on the fact that Merck used ambiguous language on the label. Moreover, Plaintiff asserts that Dr. Dunn's testimony clearly demonstrates that she may have changed her prescribing decisions had she known more about the dangers of Fosamax.

This Court has found that Dr. Parisian's expertise and background "as a Medical Officer at the FDA" qualifies her "to offer testimony about regulatory requirements relating to the development, testing, marketing, and surveillance of prescription drugs." In re Fosamax Prods. Liab. Litig., 645 F.

Supp. 2d 164, 190 (S.D.N.Y. 2009). Therefore, the only remaining issue is whether this opinion is relevant in this case; that is, whether more information in the label would have changed Dr. Dunn's prescribing decisions. As noted above, Dr. Dunn has offered conflicting testimony about what information was conveyed to her by the 2005 label. Depending on which of Dr. Dunn's statements the jury decides to credit, Dr. Parisian's opinion on the 2005 label be relevant. Therefore, her testimony on this issue is admissible.

ii. Opinion that Merck Should have Used a Different Header for its ONJ Precaution

At oral argument, Plaintiff's counsel represented that he will not elicit testimony from Dr. Parisian related to this issue. Therefore, the motion is denied as moot.

iii. Opinion that Merck Should have Warned that Fosamax "Causes" ONJ

Dr. Parisian testified that the Fosamax label need not have used the term "causation" in describing the relationship between Fosamax and ONJ; rather, she stated that the label should include a warning that Fosamax is "associated" with ONJ. As a result, Merck argues, Dr. Parisian should not be permitted to opine that Merck should have warned prescribing physicians that Fosamax "causes" ONJ.

Plaintiff argues that Dr. Parisian should be permitted to testify that Merck should have conveyed the causation information by means other than its label, such as a "Dear Doctor" letter. Plaintiff states that Dr. Parisian has made clear that, while the appropriate language for a drug label is the term "associate," other materials distributed by Merck should have used the term "causation" in describing the link between Fosamax and ONJ.

Merck's motion to exclude this testimony is granted for two reasons. First, Dr. Parisian's expert report did not include the opinion that Merck should have used Dear Doctor letters to tell physicians that Fosamax "causes" ONJ. LaSalle Bank Nat'l Assoc. v. CIBC Inc., No. 08 Civ. 8426, 2012 WL 466785, at *9 (S.D.N.Y. Feb. 14, 2012) ("The expert's report operates to limit the scope of the testimony that can be elicited from the expert. Opinions that are not disclosed in the expert's report cannot be offered."). Second, Dr. Parisian has already testified that the term "association" is adequate language for the label. It defies logic that Dr. Parisian would argue that Merck should issue additional warnings that conflict with the FDA approved language.

iv. Opinion About a "Black Box" Warning for ONJ

Plaintiff represents that Dr. Parisian does not intend to discuss a "Black Box" warning. Therefore, the motion is denied as moot.

v. Opinion that Merck Should have Warned of the Risk for Jaw Amputation

Merck urges the Court to exclude Dr. Parisian's opinion that Merck should have warned that ONJ could lead to jaw amputation or other permanent jaw damage. According to Merck, such an opinion is irrelevant because Plaintiff did not undergo a jaw resection.

Plaintiff avers that Dr. Dunn would have discussed the possibility of jaw amputation with her patients, which "obviously" would have resulted in Scheinberg's stopping Fosamax.

Dr. Parisian's opinion as to the possibility of jaw amputation or permanent jaw damage is inadmissible. This opinion is irrelevant in this case because, according to Plaintiff's expert, her jaw was fully healed by mid 2007.

vi. Opinion that Merck Should have Warned that the Risk for ONJ Increased with Long-Term Fosamax Usage

Merck states that Dr. Parisian's opinion that Merck "should have known through a review of medical literature pertaining to bisphosphonate-related ONJ" that the risk for ONJ increased the

longer one used Fosamax should also be excluded. According to Merck, Dr. Parisian bases this opinion on an article that was published the year after Plaintiff's tooth extraction and therefore is irrelevant to the facts of this case. Plaintiff suggests that Merck "has simply forgotten" that the position paper cited by Dr. Parisian included references to numerous publications that pre-date April 2006.

Dr. Parisian reports that "[b]y 2006 . . . Merck knew (or should have known through a review of medical literature . . .) that the risk of ONJ increased with additional usage." This statement indicates that the cumulative effect of the reports on Fosamax's efficacy with prolonged usage would have put Merck on notice of the issues related to prolonged use of Fosamax by 2006. Plaintiff's contention that some publications that reported on the effects of prolonged use of Fosamax predate 2006 is irrelevant, as Dr. Parisian did not state that any single publication was sufficient to put Merck on notice. Therefore, Merck's motion is granted.

vii. Opinion that Merck Should have Warned that Fosamax is "Stronger" than Other Oral Bisphosphonates

Merck seeks to exclude Dr. Parisian's opinion that Merck should have warned that Fosamax is stronger than other oral bisphosphonates and had more reports of ONJ than other oral bisphosphonates. Merck avers that Plaintiff has not offered any

expert testimony that Plaintiff would not have contracted ONJ had she taken a different oral bisphosphonate.

Plaintiff argues that Dr. Dunn testified that if she had known that there were more reports of ONJ among Fosamax patients than patients taking Actonel and Boniva combined, then she "likely would have changed [her] prescribing practices." (Bogle Decl. Ex. 6 at 197-98.) Therefore, Plaintiff states that "Scheinberg's injury clearly could have been avoided if Merck had notified physicians that Fosamax was stronger than the other oral bisphosphonates."

Plaintiff has not presented any evidence to show that Plaintiff would not have contracted ONJ if she had been on Actonel or Boniva. Therefore, testimony as to the relative strength of the various oral bisphosphonates would have no effect on proximate cause, rendering this opinion irrelevant. Accordingly, Merck's motion is granted.

viii. Opinion that Merck Should have told Physicians that There were "Hundreds of" or "Frequent" Reports of ONJ

Merck argues that Dr. Parisian should be precluded from testifying that Merck should have told physicians that there were "hundreds" of reports of ONJ among Fosamax users. Merck states that because Dr. Parisian conceded at deposition that it is impractical to include a specific number of reports of ONJ on the Fosamax label, she cannot change her testimony at trial.

Merck also asks the Court to preclude Dr. Parisian's opinion that there have been "frequent reports" of ONJ among Fosamax users on the grounds that she has offered no basis for this opinion. Dr. Parisian testified that she has not done any calculation of the prevalence or incidence of ONJ in Fosamax users, and that ONJ is a "rare event." (Parisian Depo. at 30:2-14, 31:16-18.)

According to Plaintiff, Dr. Parisian has "repeatedly insisted that Merck should have informed physicians by 2006 that it received hundreds of ONJ reports." Plaintiff suggests that Dr. Dunn's testimony implies that if she had received information about these reports, she would have relayed it to her patients, who may have opted to discontinue Fosamax.

As with any witness, inconsistencies in an expert witness's testimony do not implicate Daubert, but rather are properly addressed during cross examination. Therefore, this motion is denied.

ix. Opinion that Merck Should have Distributed a "Dear Doctor" Letter

During questioning by Merck, Dr. Dunn stated that a "Dear Doctor" letter would not have made much difference because she was familiar with the language in the label. Therefore, Merck argues, Dr. Parisian's opinion that Merck should have written a "Dear Doctor" letter is irrelevant.

Plaintiff responds that Dr. Dunn certainly would not have been swayed by a "Dear Doctor" the way Merck attorneys described it to her at deposition. Plaintiff avers that Merck attorneys described a letter that contained the same information that was in the 2005 label. However, Dr. Dunn did state that a warning with "specific information about the rate, frequency, the severity and potential causation" may have changed her prescribing practices. Thus, Plaintiff avers, if this information had been conveyed in a "Dear Doctor" letter, it may have affected Dr. Dunn's decision making.

This motion is granted for the same reason the Court granted Merck's third Daubert motion, above: Dr. Parisian's expert report did not include any discussion of a "Dear Doctor" letter. Moreover, Dr. Dunn has testified that it did not make any difference to her whether she received such a letter.

x. Opinion that Merck Should have done more To Notify Patients of the 2005 Label Change

Dr. Parisian's supplemental report states that Merck should have done more to notify patients of the 2005 change to the patient package insert. According to Merck, New York's "learned intermediary doctrine" dictates that the "duty to warn" runs to the prescribing physician, not the patient. Therefore, Dr. Parisian's opinion about Merck's duty to notify patients is

irrelevant because it has nothing to do with Merck's obligations under New York law.

Plaintiff states that "defendants may not use the 'learned intermediary' doctrine as a sword," so the doctrine is intended for product liability claims, not breach of warranty claims. Therefore, Plaintiff argues that Merck's failure to communicate its label changes to patients is relevant to her asserted claims of breach of warranty and fraudulent misrepresentation and concealment.

Because the Court has granted summary judgment on the breach of warranty and fraud claims, above, the issue of how Merck notified its patients of a label change is irrelevant. The "learned intermediary" doctrine, which applies to both design defect and failure to warn claims, "focuses on the scope of a drug manufacturer's duty to warn of the dangers of using the drug in question. That duty is fulfilled by giving adequate warning to the prescribing physician." See Spensieri v. Lasky, 94 N.Y.2d 231, 239 (1999). Whether Merck communicated with its patients would have no effect on Plaintiffs' claims. Accordingly, this motion is granted.

xi. Opinion that the FDA was in a "Rush" When it Approved Merck's 2005 Label Change

Plaintiff represents that Dr. Parisian does not intend to testify about the motivations or state of mind of the FDA.

However, Plaintiff argues that Dr. Parisian should be able to testify about Merck's negotiations with the FDA in 2005 and the fact that the length of these negotiations resulted in Merck warning of ONJ in its label several months after the other oral bisphosphonate manufacturers.

Testimony about the negotiations with the FDA, or how long the negotiations took, is inadmissible. As the Court has previously held, Dr. Parisian may not offer "a narrative history of Fosamax" because "an expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence." In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009). The Court has further ruled that it would limit Dr. Parisian's comments on exhibits "to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge." Id. The negotiations with the FDA would constitute a narrative history of Fosamax. Moreover, Dr. Parisian may not opine about negotiations to which she was not privy. Therefore, Merck's motion is granted.

xii. Opinion that Merck was the only Bisphosphonate Whose 2005 Label Differed from the FDA's Proposed Label

Merck argues that Dr. Parisian should be precluded from "erroneously" testifying that Fosamax was the only oral

bisphosphonate manufacturer who adopted an ONJ precaution that differed from what the FDA proposed. Merck avers that Dr. Parisian conceded at deposition that Actonel also adopted a precaution that differed from that was originally proposed by the FDA. Therefore, Merck proffers that this opinion is wrong and should be excluded.

Plaintiff responds that Dr. Parisian has consistently maintained that Merck is the only bisphosphonate manufacturer to remove "any reference to ONJ" in the label. Further, although Actonel's label was different from the FDA's proposal, Dr. Parisian has testified that it label was actually stronger than the one proposed by the FDA. Therefore, Plaintiff argues that she should be permitted to testify as to the "relative weakness of Merck's 2005 ONJ precaution for Fosamax" as compared to other bisphosphonate manufacturers.

This testimony is inadmissible as the language of the different drug labels speaks for itself. The jury does not need Dr. Parisian to compare the strength of the labels; jurors will be able to read the labels and conduct this comparison on their own.

xiii. Opinion About Merck's August 2006 Adjudication of ONJ Reports

In August 2006, Merck conducted a review of its adverse event reports to determine how many Fosamax users had contracted

ONJ (the "adjudication"). Dr. Parisian's report criticizes the adjudication. Merck seeks to preclude this criticism as irrelevant in light of Scheinberg's injury date. Another one of Plaintiff's experts – Dr. Kraut – testified that Scheinberg would have needed to stop taking Fosamax six months before her tooth extraction to avoid ONJ. Therefore, Merck argues that its actions after April 30, 2006 cannot be a proximate cause of Plaintiff's injury.

In response, Plaintiff urges that Merck was at all times obligated to "continue to test and study the relationship between its drug and the adverse events." Plaintiff also notes that the Court "has repeatedly concluded that plaintiffs may properly produce evidence of Merck's failure to conduct studies on Fosamax and ONJ." Finally, Plaintiff states that Merck's failure to disclose findings of its adjudication impacts prescribing practices of physicians like Dr. Dunn.

Dr. Parisian's testimony as to the August 2006 adjudication has no relevance in this case. Regardless of what Merck's adjudication would have revealed, it could not have affected Scheinberg a mere two months before her tooth extraction. This is particularly true in light of the testimony from Plaintiff's expert, Dr. Kraut, that Scheinberg would have had to stop taking Foasmax six months before October 30, 2006, i.e., April 30, 2006, to avoid ONJ.

xiv. Opinion About Merck's Interactions with the ASBMR

Merck argues that Dr. Parisian's opinion that Merck understated the number of ONJ Reports during a November 2006 conference call with ASBMR should be excluded as irrelevant. As an initial matter, Merck denies the allegation. Alternatively, Merck argues, its actions in November 2006 have no bearing on this case, where Plaintiff's tooth extraction occurred before the call.

Plaintiff states that this testimony is relevant because it shows that Merck "manipulated" the data about Fosamax and ONJ, and should be admitted if Defendant "opens the door." According to Plaintiff, it "fully expects Merck to elicit testimony from Dr. Dunn about the fact that she did not stop prescribing Fosamax after becoming aware of ONJ. If Merck elicits any testimony from Dr. Dunn concerning whether she prescribed Fosamax after 2006 or uses the ASBMR task force paper, then Plaintiff must be permitted to show Merck's manipulation of this data through testimony from Dr. Parisian."

Dr. Parisian's opinion about Merck's representations during the November 2006 conference call should be excluded because it has no relevance to this case. The conference call occurred after Plaintiff's tooth extraction and thus could not have affected her.

xv. Opinion About Merck's Correspondence with the FDA

As Plaintiff represents that Dr. Parisian does not intend to offer testimony about whether Merck provided all of its adverse event reports to the FDA, this motion is denied as moot.

xvi. Opinion About Merck's Non-Compliance with Federal Regulations

Finally, Merck argues that Dr. Parisian's opinion that Merck violated 21 C.F.R. §§ 314.80(b) and 314.70 should be excluded because she misinterprets the statutes. Dr. Parisian states that section 314.80(b) required Merck to conduct an epidemiological study of Fosamax after receiving non-ONJ adverse event reports. Similarly, Dr. Parisian says that under § 314.70, Merck was required to update the "instructions for use" section of the label with Dr. Mucci's draft analysis regarding Fosamax's fracture reduction efficacy. Merck avers that the statutory language merely "permits" label changes, and the fact that the FDA approved the label demonstrates that the FDA did not find a regulatory violation.

Plaintiff responds that this Court has consistently admitted testimony about Merck's violations of federal regulations, including § 314.70, finding that it is "qualified expert opinion" that is based on "appropriate methodology."

This issue has been directly addressed by the Court and Merck has merely repeated its prior motions that have previously

been denied. The Court will adhere to its prior rulings: Dr. Parisian's testimony as to Merck's compliance with these regulations is grounded in her qualified expert opinion and therefore admissible. See In re Fosamax Prods. Liab. Litig., 06 MD 1789, 2010 WL 4242702 at *2 (S.D.N.Y. Oct. 27, 2010) ("Although the Court takes no position on the accuracy of Dr. Parisian's conclusions, Dr. Parisian's testimony represents her qualified expert opinion about what reasonable steps drug manufacturers should take to comply with the legal duties imposed by the FDCA.").

V. Plaintiff's Daubert Motions

A. Dr. Barry Gruber

Plaintiff objects to two issues to which Dr. Gruber – Defendant's expert witness on osteoporosis and bisphosphonates – will testify.

i. Motion To Preclude Dr. Gruber's Testimony that Plaintiff Suffered a Fragility Fracture in 1994

Plaintiff argues that Dr. Gruber should not be permitted to testify to his opinion that Scheinberg suffered a fragility fracture of her left humerus (upper arm) in 1994. This fact comprises part of the foundation for Dr. Gruber's opinion that Scheinberg was osteoporotic, not osteopenic. According to Plaintiff, at deposition Dr. Gruber only identified an insurance record to support his statement that Scheinberg suffered a

fragility fracture. Plaintiff avers that Dr. Gruber does not have an adequate basis to testify as to whether Ms. Scheinberg suffered a fragility fracture, particularly since the opinion contradicts Dr. Dunn's testimony that Scheinberg was osteopenic.

Merck argues that Dr. Gruber's testimony about the fragility fracture is admissible because it is based upon his personal experience. Dr. Gruber explained that his "experience in taking histories from patients" is that when a patient does not remember experiencing a fracture, then that fracture is a fragility fracture. Because Scheinberg has no memory of her 1994 fracture, Dr. Gruber concluded that she suffered a fragility fracture. Moreover, Merck contends that while Dr. Gruber relies on both an insurance record and a Montefiore Medical center record, there is no legal basis for Plaintiff's argument that non-medical records are insufficient basis for an expert opinion. Finally, Merck asserts that Dr. Dunn's conflicting opinion as to the fragility fracture is no basis for exclusion of Dr. Gruber's testimony. "If two contradictory opinions meet the threshold of reliability, it is the function of the factfinder" to determine which is credible. (Def. Opp. at 5.)

The motion is denied. Dr. Gruber's opinion is based on his personal and professional experience. Plaintiff will be able to cross examine Dr. Gruber about the basis for his opinion,

including the records in question. Moreover, to the extent there is a suggestion that the fracture happened in the ulna, not the humerus, this issue may be explored on cross examination.

ii. Motion To Preclude Dr. Gruber's Testimony that Scheinberg's Diabetes Contributed to or Caused Scheinberg's Infection or Slowed Healing Following her Tooth Extraction

Dr. Gruber stated that Scheinberg had "poorly controlled" diabetes, which was a factor in her infection and/or slowed healing. Plaintiff argues that (1) Dr. Gruber is not qualified to assess whether Scheinberg's diabetes was "uncontrolled," and (2) he has not identified a factual or scientific basis for the assertion that diabetes contributes to delayed healing or infection in the mouth.

First, Plaintiff notes that Dr. Rita Louard, "Scheinberg's well-credentialed treating endocrinologist" testified that Plaintiff's diabetes was "well controlled." Plaintiff avers that Dr. Gruber, who refers his patients with diabetes to a diabetic specialist, should not be permitted to contradict Dr. Louard's testimony. "Dr. Gruber, by his own admission, seeks to offer opinion testimony in a field that is outside his area of expertise."

Second, Plaintiff points to Dr. Gruber's statement that there "is a paucity of data" as to the ability of a diabetic to

heal following tooth extraction as ground for exclusion. (Gruber Depo. at 111.) Dr. Gruber also stated that there are no studies that compare the post-tooth extraction healing capability of a non-diabetic with that of a diabetic. (Id.)

In response, Defendant reiterates that Dr. Louard's contrary opinion does not render Dr. Gruber's opinion inadmissible. Moreover, Defendant notes that this Court has previously held that Dr. Gruber's expertise extends beyond oral surgery. Defendant states that since Dr. Gruber has experience treating patients with diabetes, he is qualified to offer this opinion. With respect to his ability to opine as to the effects of diabetes on the pace of maxillofacial healing, Dr. Gruber testified:

> Q. And can you just very briefly, if you don't mind, explain how your role, your specialty, your expertise as an immunologist relates to diabetes and the management of diabetes?
> A. I think I can comment on the impact that diabetes might have on the immune system leading to immunocompromised host factors because of my background and my understanding of the immune system, both through rheumatology and diagnostic and clinically immunology training.
> Q. Do you treat patients who have diabetes, Dr. Gruber?
> A. Yes.
> Q. Do you treat the complications of diabetes in connection with treating those patients?
> A. Yes. There are a number of complications that have their domain in rheumatology and in musculoskeletal disease that I treat day in and day out.
> Q. And does that include the effect of the disease on the immune system?
> A. Yes.

(Gruber Depo. 160:8-161:4.) Therefore, Defendant argues, Dr. Gruber's opinion is "firmly grounded in his experience as a rheumatologist."

Next, Merck asserts that Dr. Gruber's basis for his contention that diabetes can cause or contribute to delayed healing is more than adequate. "[A]lthough Dr. Gruber conceded that there is a 'paucity of data' on that specific point," he has coupled scientific data with his rheumatology and immunology experience to make a "well reasoned inference."

This motion is granted in part and denied in part. Dr. Gruber's expertise renders him capable of opining on how various maladies affect maxillofacial healing, specifically whether diabetes slowed Scheinberg's healing. Accordingly, Dr. Gruber may testify as to the effect of diabetes on the healing process in the oral cavity. The fact that Plaintiff's expert may disagree with him is no grounds for exclusion. Dr. Gruber cannot, however, testify as to whether Scheinberg's diabetes was "uncontrolled," as his expertise does not extend to a patient's relative control of her diabetes.

B. Dr. Robert Glickman

Defendant has retained Dr. Glickman as its oral surgery expert in this case. Plaintiff seeks to exclude certain parts of his testimony.

i. Motion To Preclude Dr. Glickman from Testifying that Scheinberg had Osteomyelitis

According to Plaintiff, during the Boles litigation, Dr. Glickman testified that without a histopathologic confirmation, he cannot diagnose what type of osteomyelitis a patient has (histopathology is the microscopic examination of diseased tissue). In this case, Dr. Glickman stated that he relied on radiographs for his opinion that Scheinberg had osteomyelitis and no histopathology of her jaw bone was conducted. Plaintiff proffers that Dr. Glickman testified during Boles that radiographs were insufficient to diagnose osteomyelitis.

Defendant responds (1) that Dr. Glickman never testified that a diagnosis of osteomyelitis cannot be made without histopathology, and (2) Dr. Glickman's diagnosis of osteomyelitis is to a reasonable degree of medical certainty, which is sufficient under Rule 702.

First, Defendant states that Plaintiff has taken Dr. Glickman's testimony about histopathology from the Boles litigation out of context. According to Defendant, Dr. Glickman was able to testify that there was "a very high likelihood that" Boles had osteomyelitis, based upon evidence that did not include a histopathology report:

> Q. Can you say to a reasonable degree of medical certainty that she had osteomyelitis before the summer of 2002?

> A. Well, the diagnosis of osteomyelitis would have to be made in several forms. One would be the clinical presentation, the other would be the radiographic interpretation. And the final one, of course, would be the histopathological interpretation. So if I had bone specimens before the summer of 2002, then I could answer you with a definite yes or no. But her clinical presentation at the time at the need for the extractions and her subsequent course indicated a very high likelihood that she had had or was developing an osteomyelitis.
> Q. Can you say to a reasonable degree of medical certainty that she had osteomyelitis before the summer of 2002?
> A. I don't think that would be the way I would answer. I think the answer would be based on her clinical symptoms and the radiographic imaging that I've seen that the likelihood of osteomyelitis was very high in this individual.
> Q. But my question – I get to ask the questions, you get to answer them. My question is, can you say to a reasonable – listen to my words because they have legal meaning. Can you say to a reasonable degree of medical certainty that Shirley Boles had osteomyelitis before the summer of 2002?
> A. You can't answer medical conditions like that because they require various analyses in order to arrive at a diagnosis. So the signs and symptoms of osteomyelitis are so varied and it's so dependent on the histopathological confirmation, that the only way I can say definitively yes or no would be with that. But her presentation was consistent with osteomyelitis.

Glickman Depo. 33:4-35:6. Defendant avers that Dr. Glickman's testimony demonstrates only that histopathology is necessary to make a definitive diagnosis of osteomyelitis.

Second, Defendant argues that the Court should not require Dr. Glickman to have consulted a histopathology report to form the opinion that Scheinberg had osteomyelitis. In Merck's view, Dr. Glickman can determine that there is a "very high likelihood" that Scheinberg had osteomyelitis, which is a sufficient basis for admission under Daubert. Merck argues

that, by forcing Dr. Glickman to point to a histopathology report, Plaintiff is attempting to force Dr. Glickman to satisfy a "100% certainty" standard.

The motion is denied. Although Dr. Glickman cannot say "for certain" that Scheinberg had osteomyelitis, absolute certainty is not the standard. Dr. Glickman has testified that there is a "very high likelihood" that Scheinberg had osteomyelitis, which satisfies the standard for expert testimony. Plaintiff will have the opportunity to question the certainty of this diagnosis on cross examination.

ii. Motion To Preclude Dr. Glickman's Testimony that Scheinberg had Uncontrolled Diabetes and that it Caused or Contributed to her ONJ

Similar to her motion regarding Dr. Gruber's testimony on this issue, Plaintiff argues that Dr. Glickman should not be permitted to contradict Scheinberg's doctors' opinion that Scheinberg was a controlled diabetic. Merck represents that Dr. Glickman does not intend to offer an ultimate opinion on whether Scheinberg's diabetes was controlled.

Plaintiff also asks the court to exclude Dr. Glickman's "ipse dixit" opinion about diabetes and its effect on delayed healing. According to Plaintiff, the only article Dr. Glickman identified in support of his opinion that diabetes has an effect on healing was from the mid-1990s and involved an animal study:

> Q: And do you think that's good information to look at animal or rat studies to determine evidence about human diabetics and their ability to heal?
> A: . . . this is core knowledge, this is like, you know, first day dental school knowledge.
> Q: . . . Do you think that's good science for you to rely upon in support of this testimony that you've got about diabetics and the capacity to heal in the mouth?
> A: No, it wouldn't be the only article, just one that I can think of. I mean, there's thousands of articles. If you do a Google search on this, I did one a couple weeks ago and I think I couldn't even – it just blew the machine, that's how many articles there were on it.

(Glickman Depo. 147.)

Merck responds that "questioning relating to support for the proposition that diabetes has an effect on wound healing is, in this context, akin to asking a lay witness for support that the sun rises in the east." Defendant states that Plaintiff's expert, Dr. Kraut, even agreed with the proposition that diabetes can be a factor in delayed healing. (Kraut Depo. 128:6-13 ("Q. So am I correct, then, that you couldn't determine whether or not a patient with diabetes would be at an increased risk for infection? . . . A. Diabetics have an increased risk of infection. That is known, and I will agree to that.").

Dr. Glickman's opinion on the correlation between diabetes and slowed healing is admissible as specialized knowledge. His experience in treating patients with diabetes renders him capable of opining on the effect of diabetes on maxillofacial healing.

iii. Motion To Preclude Dr. Glickman's Testimony About Scheinberg's Asthma and its Effect on Delayed Healing or ONJ

As Merck has agreed not to raise this issue during the examination of Dr. Glickman, this motion is denied as moot.

iv. Motion To Preclude Dr. Glickman from Testifying that Smoking had an Effect on Scheinberg's Delayed Healing or ONJ

As Merck has agreed not to raise this issue during the examination of Dr. Glickman, this motion is denied as moot.

v. Motion To Preclude Dr. Glickman's Testimony that Scheinberg Had Osteoporosis, or that Osteoporosis Contributed to Her Delayed Healing or ONJ

Merck states that Dr. Glickman will not testify about (1) whether Plaintiff had osteoporosis or (2) the effect of osteoporosis on Plaintiff's oral condition. However, Merck represents that Dr. Glickman will testify regarding the effect of Plaintiff's low bone mass on her jaw's ability to heal, consistent with his case-specific expert report. (Glickman Report 1-2.)

Plaintiff responds that this testimony is inadmissible, because Dr. Glickman does not provide support for his opinion that low bone mass causes delayed healing.

As Dr. Glickman's expertise in oral surgery is undisputed, his opinion as to the effect of various maladies on healing in the oral cavity is admissible. Therefore, Dr. Glickman is

permitted to address the opinion he asserted in his expert report as to low bone mass and delayed healing.

vi. Motion To Preclude Testimony that Scheinberg's Shingles Contributed to Her Delayed Healing or ONJ

Plaintiff seeks to exclude Dr. Glickman's opinion that Scheinberg had cultures which confirmed the presence of the shingles virus, on the grounds that he could not identify the cultures, or the physician who took the cultures, at deposition. Next, Plaintiff asks the Court to preclude Dr. Glickman from opining that Scheinberg's shingles caused her ONJ, because he conceded at deposition that shingles is not a cause of ONJ.

Merck responds that Dr. Glickman does not intend to offer the opinion that shingles caused or contributed to Plaintiff's jaw condition. Rather, he will testify that her "bout with [shingles] indicates that her immune system was compromised at the precise time she needed her immune response to assist with the healing from her extraction and the surrounding infection." (Glickman Report at 3.) According to Merck, while shingles is not an element in the causal chain, it is an "indication" of a compromised immune system, and therefore relevant.

Merck has not demonstrated that shingles has anything to do with ONJ. Unless it can demonstrate a connection between shingles and ONJ, then Dr. Glickman will not be permitted to opine on this issue.

vii. Motion To Preclude Dr Glickman from Relying upon Hearsay Statements and CTX Testing Data in Support of his Opinions

First, Plaintiff argues that this Court has already determined that Plaintiff's witnesses may not cite CTX testing in support of causation theories; therefore, Plaintiff says that Dr. Glickman should be precluded from relying on CTX tests during his testimony. Second, Plaintiff argues that Dr. Glickman should not be permitted to testify to his "discussions with colleagues at conferences," even if he uses such hearsay as the basis for his theories. Finally, Plaintiff argues that when discussing his opinion that Scheinberg's six-month cessation of Fosamax does not explain why Scheinberg's jaw healed, Dr. Glickman "cited one article, his own, concerning CTX testing, hearsay discussions with endocrinologists, surgeons, and conferences."

As an initial matter, under Rule 703, Dr. Glickman may rely upon hearsay in rendering his opinions, but such hearsay may not be cited to the jury. As to the CTX reports, Merck represents that "Merck and Dr. Glickman intend to abide by the Court's prior rulings with regard to CTX testing" and will not offer testimony as to CTX reports and specific causation. Therefore the motion is granted in that Dr. Glickman may not cite hearsay to the jury, and denied as moot in all other respects.

viii. Motion To Preclude Dr. Glickman from Offering Testimony Contrary to the Points he Conceded at Deposition

Plaintiff complains that there were only two hours for the case-specific discovery deposition of Dr. Glickman. During that deposition, Dr. Glickman made three factual concessions upon which Plaintiff's counsel "relied." Now, Plaintiff argues that "pursuant to Federal Rule of Civil Procedure 37, this Court should preclude Dr. Glickman from offering testimony which conflicts with the points he conceded in discovery depositions." Specifically, Plaintiff points to the following statements Dr. Glickman made at deposition:

> 1) That he does not intend to testify that Scheinberg's Tooth #31 was mobile. During the Boles trial, Dr. Glickman testified that the presence of mobile teeth, coupled with radiology, told him that Boles had "chronic periodontal infection."
> 2) That there was no periapical infection, jaw trauma, or foreign body left behind after Scheinberg's tooth extraction. These were included in Dr. Glickman's differential diagnosis, but he subsequently ruled them out, as he testified at deposition.
> 3) That he cannot say that Scheinberg had osteomyelitis before the October 30, 2006 extraction.

Merck responds that the Court should not "enter an order barring alleged unspecified contrary testimony from Dr. Glickman on the highly specific topics listed." According to Merck, none of the specific topics listed are proper grounds for a Daubert challenge, and Merck suggests that cross-examination is an

appropriate vehicle for Plaintiff to explore any inconsistencies in Dr. Glickman's testimony.

This motion is denied. To the extent that Dr. Glickman's statements at trial contradict his deposition testimony, Plaintiff will have the opportunity to examine Dr. Glickman about these statements on cross examination. The Court held as much in the Secrest case:

> Plaintiff does not challenge the scientific reliability of Dr. Betts' (or other potential Merck witnesses') testimony on this topic. Instead, Plaintiff argues that Dr. Betts has made statements in the past that may contradict testimony that Secrest had ONJ prior to spring 2004 or after 2005. To the extent that these prior statements call into question any testimony introduced by Dr. Betts at trial, Plaintiff will have the opportunity to cross-examine Dr. Betts about these prior statements. However, a jury would not necessarily have to accept Plaintiff's characterization of Dr. Betts' prior statements as contradicting testimony about possibly earlier or later onset of Secrest's injuries.

In re Fosamax Liab. Litig., 807 F. Supp. 2d 168, 183 (S.D.N.Y. 2011).

ix. Motion To Preclude Dr. Glickman from Using "Consistent With" Terminology, if Dr. Buch is not Permitted to Use such Terminology, Pursuant to Merck's Daubert Motion

Dr. Glickman testified that certain findings are "consistent with" long-term infection. Plaintiff states that if the Court grants Defendant's motion to exclude Dr. Buch's testimony that Scheinberg's post-extraction delayed healing was "consistent with Fosamax's effect on delayed healing following

tooth extraction," it must also exclude Dr. Glickman's testimony that uses the "consistent with" language.

Although the Court has precluded Dr. Buch's testimony on causation, it did not do so because of the "consistent with" language. Therefore, Plaintiff's motion to preclude any statement by Dr. Glickman on the grounds that it includes the phrase "consistent with" is without merit. As there is no other basis for excluding this testimony, the motion is denied.

VI. Conclusion

For the reasons stated above, Defendant's motion for summary judgment is granted with respect to Plaintiff's claims for breach of warranty, fraudulent misrepresentation and concealment, and punitive damages, but denied with respect to Plaintiff's claim for design defect and failure to warn. Merck's motions to preclude expert testimony are granted in part and denied in part. Plaintiff's motion to preclude expert testimony is granted in part and denied in part.

SO ORDERED.

Dated: New York, New York
January 7, 2013

John F. Keenan

JOHN F. KEENAN
United States District Judge